

REMARKS

The present amendment under 37 CFR § 1.114 is in response to the Final Office Action dated July 1, 2003 and further to the Notice of Appeal filed on December 30, 2003. With the above amendment, claims 13-36 and 40 have been cancelled and new claims 41 and 42 have been added. Accordingly, claims 1, 3, 4, 6-9, 11, 12, 37-39, and 41-42 are pending in the application. Claims 1 and 8 have been amended solely to expedite prosecution. No new matter has been added. Support for the amendments can be found throughout the specification as filed. Support for new claims 41 and 42 can be found, for example, at page 9, lines 11-15. Applicants note that the above amendments are made without prejudice to prosecution of any subject matter removed or modified by this amendment in a related divisional, continuation or continuation-in-part application.

With regard to the negative limitation recited in amended claims 1 and 8, Applicants submit, as discussed further below, that it was decided in *In re Johnson* that the use of negative provisos to excise a species disclosed in the prior art from the scope of a claimed genus is permissible. *See, In re Johnson*, 558 F.2d 1008, 194 U.S.P.Q. 187 (C.C.P.A. 1977).

***Rejection Under 35 U.S.C. § 112, first paragraph***

Claims 1-7 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly lacking enablement. In particular, the Action contends that, while the specification is enabling for methods of diagnosing lung damage by measuring an increase in pulmonary surfactant A (SP-A) and/or pulmonary surfactant B (SP-B), the specification does not reasonably provide enablement for diagnosing lung damage by measuring decreases in SP-A or SP-B or measuring levels of pulmonary surfactant C (SP-C) or pulmonary surfactant D (SP-D) or decreases in any of SP-A or B.

Claims 8-12 also stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly lacking enablement. In particular, the Action contends that, while the specification is enabling for methods of monitoring the changes in the extent of lung damage by measuring changes in SP-A and or SP-B, the specification does not reasonably provide enablement for measuring changes in SP-C and/or SP-D.

Without acquiescing to the above grounds for rejection and solely to expedite prosecution, Applicants have removed reference to SP-C and SP-D in the claims. Applicants reserve the right to prosecution of any subject matter removed or modified by this amendment in a related divisional, continuation or continuation-in-part application. Accordingly, Applicants submit that the rejection has been obviated and may be properly withdrawn.

***Rejections Under 35 U.S.C. § 102***

Claims 1, 3, 4, 7, 8, 9, 38, 39, and 40 stand rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Honda (Japanese Journal of Thoracic Diseases, 34 Suppl. Abstract only, December 1996) and by Abe *et al.*, (Japanese Journal of Thoracic Diseases, 33 (11):1219, Abstract Only, November 1995). Claims 1, 6-9, 11, 12, and 37-40 stand rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Ian R. Doyle (Advances in Critical Care Testing, Eds. List, Muller and McQueen, Springer-Verlag Telos, January 1997). In particular, the Action contends that lung damage is necessarily and inherently a component of idiopathic interstitial pneumonia (IIP) as disclosed in Honda. Further, the Action contends that Abe *et al.*, teach detecting serum levels of SP-A in patients with IIP and that the SPA level correlated closely with the clinical course and rose significantly during exacerbations of IIP, and that lung damage is necessarily a component of IIP. The Action asserts that Doyle specifically teaches the association of the levels of SP-A and SP-B with lung damage in acute respiratory distress syndrome (ARDS) patients. The Action also asserts that the limitations of the claims are met by the cited prior art references given Applicants' definition of "early stage lung damage".

Applicants respectfully traverse the rejection. Applicants note that claim 40 has been cancelled without prejudice. Applicants submit that the claims as amended are not anticipated by Honda, Abe *et al.*, or Doyle. In particular, the claims as amended recite a method of diagnosing lung damage in a mammal, or a method of monitoring for changes in the extent of lung damage in a mammal, which mammal is not exhibiting a symptom specific to lung damage, said method comprising screening for an increase in the levels of SP-A and/or SP-B in the body fluid of said mammal relative to a normal reference level or screening for the modulation of the levels of SP-A and/or SP-B in the body fluid of said mammal relative to a normal reference level. Additionally, new claims 41 and 42 recite methods of diagnosing lung damage in a

mammal, or alternatively, monitoring for changes in the extent of lung damage, during a period in which the onset of lung damage cannot otherwise be confirmed without the aid of one or more invasive procedures.

Applicants submit that there are numerous clinical symptoms of lung damage which are non-specific. As would be recognized by the skilled artisan, the main symptoms which one may present with in the early stages of lung damage include shortness of breath, fast breathing, tachycardia, cough, chest pain and low oxygen levels in the blood. However, each and every one of these symptoms is many times a symptom of a condition which is not associated with lung damage (See attached Table). Applicants submit that the prior art does not teach or suggest a method of diagnosing lung damage in a mammal, or a method of monitoring for changes in the extent of lung damage in a mammal, which mammal is not exhibiting a symptom specific to lung damage. On the contrary, Applicants submit that, as would be readily recognized by the skilled artisan, patients with advanced IIP and ARDS present with symptoms that are specific to lung damage and further present with lung damage that can be confirmed without the aid of one or more invasive procedures. Accordingly, the cited art also does not teach or suggest the methods of the present invention and therefore, do not anticipate the claimed invention. Applicants respectfully request withdrawal of the rejection.

With regard to the negative proviso recited in amended claims 1 and 8, Applicants submit, as noted above, that it was decided in *In re Johnson* that the use of negative provisos to excise a species disclosed in the prior art from the scope of a claimed genus is permissible. In *In re Johnson*, the applicants claimed a genus of certain thermoplastic polymers and, during prosecution, amended the claims to exclude several known prior art species that fell within the claimed genus. In reversing the Board's decision that no basis existed in the application for the "limited genus" claimed by the applicants, the CCPA held that:

"The notion that one who fully discloses, and teaches those skilled in the art how to make and use, a genus and numerous species therewithin, has somehow failed to disclose, and teach those skilled in the art how to make and use, that genus minus two of those species, and has thus failed to satisfy the requirements of § 112, first paragraph, appears to result from a

hypertechnical application of legalistic prose relating to that provision of the statute.” *Id.* at 196.

The CCPA further noted that the “specification, having described the whole, necessarily described the part remaining” and that the applicants “are merely excising the invention of another, to which they are not entitled, and are not creating an ‘artificial subgenus’ or claiming ‘new matter’”. *Id.* at 196.

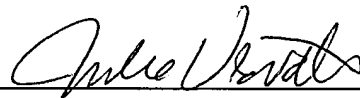
Similarly, in the present application, Applicants have merely amended the claims in order to advance prosecution to exclude a species allegedly disclosed in the prior art from a genus which is fully supported in the specification. Accordingly, Applicants submit that the written description requirement is satisfied for the amended claims.

The Director is authorized to charge any additional fees due by way of this Amendment, or credit any overpayment, to our Deposit Account No. 19-1090.

Applicants respectfully submit that all the claims remaining in the application are now believed allowable. Favorable consideration and a Notice of Allowance are earnestly solicited.

Respectfully submitted,

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